June 18, 2026

Stryker Sustainability Solutions
Scott English
Principal Regulatory Affairs Specialist
1018 W Drake Dr.
Tempe, Arizona 85283

Re: K260636
Trade/Device Name: Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, NUJ
Dated: May 22, 2026
Received: May 22, 2026

Dear Scott English:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) provided in the document titled “Predetermined Change Control Plan for Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating Revision Level: Rev. A Document Number: RGD13383”. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR

830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.06.18 15:45:42 -04'00'

For
Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260636

Device Name
Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating

Indications for Use *(Describe)*
The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, and so forth.

The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider without Nano-coating for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

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510(k) SUMMARY

Submitter:
Stryker Sustainability Solutions
1810 W. Drake Drive
Tempe, Arizona 85283

Contact:
Scott English
Principal Regulatory Affairs Specialist
901-451-1456 (o)
480-763-5310 (f)
scott.english@stryker.com

Date of Preparation: June 18, 2026

Name of Device:

Trade/Proprietary Name: Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification Information: Electrosurgical, Cutting & Coagulation Accessories (21 CFR§878.4400, Product Code GEI, Class II)

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
LXMJ23L LXMJ37L LXMJ44L LXMJ23S LXMJ37S LXMJ44S	K223158	LigaSure XP Maryland Jaw Sealer/Divider	Covidien

Device Description:

The Remanufactured LigaSure XP Maryland Jaw Sealer/Dividers Without Nano-coating are bipolar electrosurgical instruments intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. Remanufactured LigaSure XP Maryland Jaw Sealer/Dividers can be used on vessels (arteries and veins) up to and including 7mm. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymphatics) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue. The Remanufactured LigaSure XP Maryland Jaw Sealer/Dividers are available in two handle styles: One-Step Sealing and Latching Handle. Each handle style has three available shaft lengths: 23cm, 37cm, and 44cm. The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws. For One-Step Sealing models, the mechanism is also used for activating RF energy and must be held closed during vessel sealing and cutting. For Latching Handle models, the mechanism is locked in place allowing the jaws to remain in the closed position until engaged a second time to unlock.
- An activation button for generator power to initiate vessel sealing. For One-Step Sealing models, this is located at the bottom of the handle. For Latching Handle models, this is located on the back of the handle.
- A trigger for actuating the blade. The blade can only be deployed when the jaws are closed.
- A rotation wheel to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator. The instrument attached to the generator via a cable with a connector that identifies the instrument type to the generator.

The Original Manufacturer applies a non-stick coating the jaws of the device to reduce tissue sticking. When remanufacturing the LigaSure XP Maryland Jaw Sealer/Divider, Stryker Sustainability Solutions will not apply a non-stick coating to the jaws of the device.

The instrument is compatible with the Covidien Valleylab FT10 Energy Platform.

The scope of the submission only includes the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating and not the Valleylab FT10 Energy Platform that is used to power the device, or the footswitch that connects to the generator. Stryker Sustainability Solutions does not reprocess, remanufacture, or market the generators or footswitch.

Intended Use:

The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, and so forth.

The Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider without Nano-coating for these procedures.

Indications for Use Comparison:

The indications for use for the proposed device are the same in comparison to the predicate device.

Technological Comparison:

The design, materials, and intended use of the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating are equivalent to the predicate device. The mechanism of

action of the remanufactured device is identical to the predicate device in that the same standard mechanical design, materials, and size is utilized. There are no changes to the claims, intended use, clinical application, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' remanufacturing of the device includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations. The only differences between the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating and the predicate LigaSure XP Maryland Jaw Sealer/Divider are that the device is remanfuactured, and some device components are replaced with equivalent components during the reprocessing operation. Additionally, the Original Manufacturer applies a non-stick coating to the jaws of the device. During remanufacturing, Stryker Sustainability Solutions does not apply a non-stick coating to the jaws of the device.

	Predicate Device	Subject Device
Uses	Single Patient Use	Single Patient Use
Device Length	23cm, 37cm, 44cm	23cm, 37cm, 44cm
Device Diameter	5mm	5mm
Mechanism for Cutting	Mechanical – User actuated blade	Mechanical – User actuated blade

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization
- Electrical Safety and Electromagnetic Compatibility
- Functional Performance Tests
  - Rotation Wheel Force
  - Jaw Lever Actuation Force
  - Cutting Trigger Actuation Force
  - Trocar Insertion Force
  - Jaw Open Angle
  - Blade Excursion
  - Cut Quality
  - Burst Pressure
  - Maximum Jaw and Shaft Temperature
  - Device Reliability
  - Functional Attribute Testing

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up to 7mm, including burst pressure, maximum jaw temperature, device functionality, device reliability, and functional attribute tests.

Additionally, preclinical laboratory evaluations in an animal model were performed, which included acute and chronic survival studies. The studies were done to evaluate thermal spread and the ability to achieve chronic hemostasis of vessels of the remanufactured device.

Conclusion:

The results of bench testing and preclinical laboratory evaluations demonstrate that the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating is substantially equivalent in terms of safety and effectiveness as the legally marketed predicate for the requested indications for use.

Predetermined Change Control Plan

The submission includes a Predetermined Change Control Plan (PCCP) for the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider Without Nano-coating. The PCCP established a comprehensive framework for managing a pre-planned modification to allow an additional remanufacturing cycle. It also details the methods for implementing this modification while ensuring the Remanufactured LigaSure XP Maryland Jaw Sealer/Divider remains as safe and effective as the predicate device. A summary of the proposed modification, testing methods and validation activities is provided in the table below. User communication is not required after implementation of the modification.

Modification	Test Methods and Validation Activities	Performance Requirements
Addition of one (1) remanufacturing cycle to bring the total number of remanufacturing cycles to two (2).	Devices will be subjected to Burst Pressure testing, Thermal Spread testing, and Chronic Animal Study according to *Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery: Guidance for Industry and Food and Drug Administration Staff* after 2 remanufacturing cycles.	Statistically equivalent burst pressure and thermal spread (depth and width) in comparison to the predicate device. No hemostatic complications attributed to the remanufactured device as noted by the pathologist at the 21-day necropsy in the Chronic Animal Study.
	Devices will be subjected to Jaw Clamp Force testing, Burst Pressure testing, Maximum Jaw and Shaft Temperature, and Device Reliability testing after 2 remanufacturing cycles and accelerated aging.	Statistically equivalent Jaw Clamp Force, Burst Pressure, Maximum Jaw and Shaft Temperature, and Device Reliability in comparison to the predicate device.
	The devices will be subjected to Biocompatibility testing according to the requirements of ISO 10993-1, ISO 10993-5, ISO 10093-7, ISO 10993-10, and ISO 10993-11 after 2 remanufacturing cycles.	Cytotoxicity samples shall have a score of 2 or less. Sensitization samples must indicate a grade of non-sensitizer. Irritation samples must indicate a grade of slight or negligible. Systemic Toxicity Systemic Injection samples must indicate a grade of non-toxic or negligible. Materials Mediated Pyrogen samples must indicate a grade of non-pyrogenic.

	The devices will be subjected to a native soil characterization after 2 clinical uses to determine if devices that have been clinically used twice create a new worst-case challenge to the cleaning process. If a new worst-case challenge to the cleaning process is identified, a cleaning validation will be performed to ensure the twice remanufactured device still meets the acceptance criteria for cleanliness.	Native soil characterization results of devices that have been clinically used twice are less than or equal to the worst-case challenge (process challenge device) to the cleaning process. If a cleaning validation is required, twice-remanufactured devices still meet the visual, protein, and hemoglobin acceptance criteria.
	The devices will be subjected to Bioburden Enumeration testing after 2 remanufacturing cycles according to ISO 11737-1 to confirm the 2x remanufactured devices do not create a new worst-case challenge to the sterilization cycle.	Bioburden Estimates for devices after 2 remanufacturing cycles shall remain below the alert and action limits established for the devices after 1 remanufacturing cycle.
	Devices will be subjected to Electromagnetic Compatibility and Electrical Safety testing required by IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 after 2 remanufacturing cycles.	Test samples must demonstrate passing results per the applicable requirements outlined in IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 for these device types.